



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Shanker GUPTA

Application No. 10/056,567

Filed: January 25, 2002

For: FORMULATION OF BORONIC ACID
COMPOUNDS

Group Art Unit: 1623

Examiner: Michael C. Henry

PATENT
Attorney Docket No. 214986
Client Reference No. E-116-0170

#8
9-12-03
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INFORMATION DISCLOSURE STATEMENT

Mail Stop
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☐ within any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date

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of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☒ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:

☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).

or

☒ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

Copies of the References

- ☒ Copies of the references listed on the enclosed Form 1449 are enclosed herewith. Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).

- ☒ A copy of Richardson et al., "A Phase 2 Study of Bortezomib in Relapsed, Refractory Myeloma," *N. Engl. J. Med.*, Vol. 348, No. 26, pp. 2609-2617 (June 2003), is enclosed herewith. The reference is not prior art to the instant application, but describes clinical trials that were conducted, at least in part, prior to the priority date of the instant application and that involved the use of the pharmaceutical composition prepared by reconstituting the lyophilized form of the compound D-mannitol *N*-(2-pyrazine)carbonyl-L-phenylalanine-L-leucine boronate. The clinical trials are not believed to constitute proper prior art to the instant application, but Applicants disclose this information for completeness sake.

- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status (check one)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

Statement under 37 CFR 1.97(e)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under 37 CFR 1.704(d)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Fees

- ☐ No fee is owed by the applicant(s).
- ☒ The **IDS Fee of \$180** under 37 CFR 1.17(p) is enclosed herewith.

In re Appln. of Gupta
Application No. 10/056,567

Method of Payment of Fees

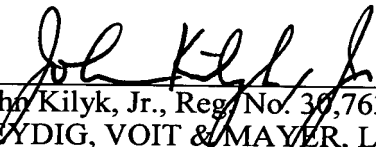
- ☐ Attached is a check in the amount of \$
☒ Charge Deposit Account No. 12-1216 in the amount of \$180.00. (A duplicate copy of this communication is enclosed for that purpose.)

Authorization to Charge Additional Fees

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

Instructions as to Overpayment

- ☒ Credit Account No. 12-1216.
☐ Refund

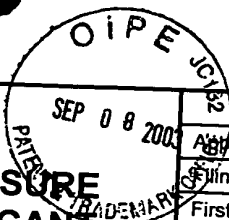


John Kilyk, Jr., Reg. No. 30,763
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: September 8, 2003

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Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	2
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Complete if Known	
Application Number	10/056,567
Filing Date	January 25, 2002
First Named Inventor	Shanker GUPTA
Group Art Unit	1623
Examiner Name	Michael C. Henry
Attorney Docket Number	214980

U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	AH	4,499,082		Shenvi et al.	2/12/85	
	AI	5,106,948		Kinder et al.	4/21/92	
	AJ	5,169,841		Kleeman et al.	12/8/92	
	AK	5,187,157		Kettner et al.	2/16/93	
	AL	5,242,904		Kettner et al.	9/7/93	
	AM	5,250,720		Kettner et al.	10/5/93	
	AN	5,492,900		LaHann	2/20/96	
	AO	5,574,017		Gutheil	11/12/96	
	AP	5,935,944		LaHann	8/10/99	
	AQ	5,990,083		Iqbal et al.	11/23/99	
	AR	2002/0188100	A1	Plamondon et al.	12/12/02	

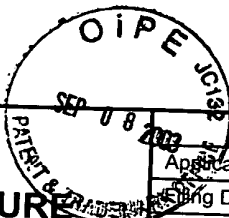
FOREIGN PATENT DOCUMENTS								
Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	AS	WO	98/35691	A1	Proscript, Inc.	8/20/98		
	AT	WO	99/15183	A1	Proscript Inc.	4/1/99		
	AU	WO	00/57887	A1	Glycosyn Pharmaceuticals, Inc.	10/5/00		
	AV	WO	02/059131	A1	Millennium Pharmaceuticals, Inc.	8/1/02		

OTHER - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.			
	AW	CIECHANOVER, "The Ubiquitin-Proteasome Proteolytic Pathway," <i>Cell</i> , Vol. 79, pp. 13-21 (October 7, 1994)			
	AX	GENNARO, "Remington: The Science and Practice of Pharmacy," 20 th Edition, Chapter 42, pp. 802-803 (2000)			
	AY	KIBBE, "Handbook of Pharmaceutical Excipients," 3 rd Edition, pp. 324-328 (2000)			
	AZ	KORCEK et al., "Absolute Rate Constants for the Autoxidation of Organometallic Compounds, Part II. Benzylboranes and 1-Phenylethylboranes," <i>J. Chem. Soc., Perkin Trans. II</i> , pp. 242-248 (1972)			
	BA	RICHARDSON et al., "A Phase 2 Study of Bortezomib in Relapsed, Refractory Myeloma," <i>N. Engl. J. Med.</i> , Vol. 348, No. 26, pp. 2609-2617 (June 2003)			
	BB	SNYDER et al., "Aryl Boronic Acids. II. Aryl Boronic Anhydrides and their Amine Complexes," <i>J. Am. Chem. Soc.</i> , 80, pp. 3611-3615 (1958)			
	BC	STELLA et al., "Development of Parenteral Formulations of Experimental Cytotoxic Agents. I. Rhizoxin (NSC-332598)," <i>International Journal of Pharmaceutics</i> , Vol. 43, pp. 191-199 (1988)			
	BD	WILLIAMS et al., "The Effects of Cooling Rate on Solid Phase Transitions and Associated Vial Breakage Occurring in Frozen Mannitol Solutions," <i>Journal of Parenteral Science & Technology</i> , Vol. 40, No. 4, pp. 135-141 (July-August 1986)			

Examiner Signature	Date Considered
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* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
 + An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

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Complete if Known

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	2	of	2
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Application Number	10/056,567
Filing Date	January 25, 2002
First Named Inventor	Shanker GUPTA
Group Art Unit	1623
Examiner Name	Michael C. Henry
Attorney Docket Number	214980

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OTHER - NON PATENT LITERATURE DOCUMENTS

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Examiner Signature

Date Considered

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